

REMARKS

The Office Action of April 5, 2007, has been received and reviewed. Claims 1, 3-8, 11, 13, 16, 22, and 24 are currently pending in the application. Claims 1, 3-8, 11, 13, 16, and 22 stand rejected. Claims 1 and 22 are amended herein. New claims 24-6 are presented herein. Basis for new claims 24-26 can be found throughout the Specification and more specifically at ¶¶ [0012], [0014], [0018], and [0019]. All amendments and claim cancellations are made without prejudice or disclaimer. No new matter has been presented. Reconsideration is respectfully requested.

Interview

The applicants' representatives would like to thank the Examiner for the courtesy extended them during the personal interview of August 20, 2007 at 2:00 p.m. The interview was helpful to the applicants and their representatives in gaining an understanding of the Examiner's concerns. At the interview, the rejections made in the Office Action of April 5, 2007 were discussed as were the Examiner's and applicants perspectives with respect to the rejections. As discussed at the interview, applicants are amending the application as previously set forth in an effort to remove outstanding issues and otherwise expedite prosecution. If the Office believes that further comments are necessary or desired describing the interview, the Examiner is kindly requested to contact applicants' undersigned attorney, and further detail will be promptly provided.

Rejections under 35 U.S.C. § 112, First Paragraph, Enablement

Claims 1, 3-8, 11, 13, 16, and 22 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly failing to comply with the enablement requirement. Applicants respectfully traverse the rejections as hereinafter set forth.

Although applicants do not agree that any of the claims lack enablement, to expedite prosecution, claims 1 and 22 have been amended herein. Specifically, claims 1 and 22 have been amended to recite "wherein said cytoplasmic domain comprises at least a JAK binding site." The Examiner notes that "the teaching of a single cytoplasmic domain as a working example that can be used in the claimed receptor is not sufficient to enable the vast genus of potential cytoplasmic

domains that are encompassed by the claimed receptor.” Office Action at page 8. Applicants respectfully submit that to satisfy the enablement requirement absolute predictability is not required; only that one of ordinary skill in the art be able to practice the invention without undue experimentation. Applicants respectfully submit that while extensive experimentation might be required to determine which recombinant receptors comprising a JAK binding site and which inhibitors would function, such experimentation would not be undue.

Two recent decisions by the Federal Circuit and the Board of Patent Appeals and Interferences (BPAI) have noted that, particularly in the biotechnological arts, even extensive experimentation in the norm and is not considered undue for the purposes of enablement. In *Falkner v. Inglis*, the Federal Circuit, in agreeing with the BPAI, notes that “the mere fact that the experimentation may have been difficult and time consuming does not mandate a conclusion that such experimentation would have to be considered undue in this art. Indeed, great expenditures of time and effort were ordinary in the field . . .” 448 F.3d 1357, 1365 (Fed. Cir. 2006). In addition, the BPAI, in the decision of *Ex parte Kubin*, noted that “[t]he amount of experimentation to practice the full scope of the claimed invention might have been extensive, but it would have been routine. The techniques necessary to do so were well known to those of skill in the art.” (83 USPQ2d 1410, 1416 (BPAI 2007).

Applicants note that it is well within the capabilities of one of ordinary skill in the art to create multiple receptors comprising a JAK binding site according to claim 1 and that these recombinant receptors can be tested using the procedures and examples outlined in the Specification. Further, in light of the recent decisions in *Falkner* and *Kubin*, such creation and testing are considered routine in the biotechnological arts and are thus not undue.

In addition, applicants respectfully submit that the cytoplasmic domains for which specific examples are provided in the specification are representative of the genus. Applicants note that example receptors are made from EpoR and LepR (*see, e.g.*, Examples 1 and 3). Applicants submit that these receptors are representative of a very large and diverse field of possible cytoplasmic domains and indicate that there is little, other than a JAK binding site, that are required for function as claimed. Thus having enabled two broadly diverse species, applicants submit they have enabled an equally broad genus. This is most easily demonstrated by reference to the attached full-length sequence alignment between the cytoplasmic domain of the

LepR (approximately amino acids 841-1165 of GeneBank Accession No. AAB09673) and the cytoplasmic domain of EpoR (approximately amino acids 249-508 of GeneBank Accession No. AAB23271). As can be seen therein, the identity between the two sequences is a small 13.7% with only 23% of the sequence even qualifying as similar. Thus, EpoR and LepR indicate the enabled functionality of highly divergent cytoplasmic domains and are thus representative of, and therefore enabling for, the genus.

In view of at least the foregoing, applicants respectfully submit that claim 1, as amended, is enabled. As such, applicants respectfully request the withdrawal of the rejection of claim 1 under 35 U.S.C. § 112, first paragraph, for lack of enablement, and reconsideration of same.

In addition, applicants respectfully submit that claims 2-8, 12, 14, 16, 18, and 27 are enabled, *inter alia*, as depending from or otherwise comprising all the elements of enabled claim 1. Accordingly, applicants respectfully request the withdrawal of the rejections of claim 2-8, 12, 14, 16, 18, and 27 under 35 U.S.C. § 112, first paragraph, for lack of enablement, and reconsideration of same.

Rejections under 35 U.S.C. § 112, First Paragraph, Written Description

Claims 1-8, 12, 14, 16, 18, and 27 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly failing to comply with the written description requirement. Applicants respectfully traverse the rejections as hereinafter set forth.

Applicants respectfully note that a claim can meet the written description requirement under *Enzo Biochem, Inc. v. Gen-Probe Inc.* through the showing of “relevant identifying characteristics *i.e.* complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.” 296 F.3d 1316, 1324 (Fed. Cir. 2002) (emphasis added). Applicants respectfully note the added emphasis on “or” which applicants submit clearly indicates that one does not have to meet each and every one of the tests outlined by the *Enzo* court, but that any one of them can be met to satisfy the written description requirement.

Although applicants do not agree that any of the claims lack written description, to expedite prosecution, claim 1 has been amended herein. Specifically, claim 1 has been amended

to recite “wherein said cytoplasmic domain comprises at least a JAK binding site.” Applicants submit that JAK binding sites are well known in the art and that there is a disclosed correlation between structure and function for JAK binding sites. *See, e.g.* page 70 of Ihle et al., Jaks and Stats in signaling by the cytokine receptor superfamily, Trends Genet., Feb. 1995, pp. 69-74, Vol. 11, No. 2; submitted in and IDS filed May 16, 2007. In light of the amendment, applicants respectfully submit that adequate written description for the recombinant receptor of claim 1 exists at least in that it has the functional characteristic of comprising a JAK binding site, which itself has a well known correlation between structure and function.

In addition, applicants respectfully submit that the cytoplasmic domains for which specific examples are provided in the specification are representative of the genus. Applicants note that example receptors are made from EpoR and LepR (*see, e.g.*, Examples 1 and 3). Applicants submit that these receptors are representative of a very large and diverse field of possible cytoplasmic domains and indicate that there is little, other than a JAK binding site, that are required for function as claimed. Thus having enabled two broadly diverse species, applicants submit they have described an equally broad genus. This is most easily demonstrated by reference to the attached full-length sequence alignment between the cytoplasmic domain of the LepR (approximately amino acids 841-1165 of GeneBank Accession No. AAB09673) and the cytoplasmic domain of EpoR (approximately amino acids 249-508 of GeneBank Accession No. AAB23271). As can be seen therein, the identity between the two sequences is a small 13.7% with only 23% of the sequence even qualifying as similar. Thus, EpoR and LepR indicate the described functionality for highly divergent cytoplasmic domains and are thus representative of, and therefore adequate to describe, the genus.

In view of at least the foregoing, claim 1 should now be in condition for allowance. As such, applicants respectfully request the withdrawal of the rejection of claim 1 under 35 U.S.C. § 112, first paragraph, for lack of written description, and reconsideration of same.

In addition, applicants respectfully submit that claims 2-8, 12, 14, 16, 18, and 27 are adequately described, *inter alia*, as depending from or otherwise comprising all the elements of adequately described claim 1. Accordingly, applicants respectfully request the withdrawal of the rejections of claim 2-8, 12, 14, 16, 18, and 27 under 35 U.S.C. § 112, first paragraph, for lack of written description, and reconsideration of same.

CONCLUSION

In light of the above amendments and remarks, applicants respectfully request reconsideration of the application. If questions remain after consideration of the foregoing, or if the Office should determine that there are additional issues which might be resolved by a telephone conference, the Office is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Respectfully submitted,



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